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September 22, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of J. Huston, P. Wils, Q. Zhu, O. Laurent, W. Marasco, & D. Scherman
Application No. 09/888,721 — Group No. 1632
Filed June 25, 2001 — Examiner C. Yaen
Bioengineered Vehicles for Targeted Nucleic Acid Delivery

(Atty. Docket No. P 23,611-A USA)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on Monday, September 22, 2003.

Arlene M. Olson

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION
UNDER 37 CFR §1.143 OF THE EXAMINER'S
REQUIREMENT FOR RESTRICTION, DATED MAY 21, 2003

Sir:

In response to the Examiner's Requirement for Restriction of May 21, 2003, applicants elect provisionally, with traverse, the Group I claims (Claims 1, 2, 4 to 8,

16 to 29, and 52), drawn to a gene-delivery compound comprising a single-chain binding polypeptide and a nucleic acid binding moiety.

Applicants traverse, however, the Examiner's Requirement. It is submitted respectfully that the Examiner's Requirement is deficient because 35 U.S.C. §121 requires that the subject matter of the claim groups be independent from each other, as well as distinct. Clearly, the inventions which are defined in the various groups of claims are not independent in that there exists a disclosed relationship amongst them. In the first instance, the claims of Groups I to VI all define a gene delivery compound comprising a single chain binding polypeptide and a nucleic acid binding moiety and the claims of Group I are generic to those of Groups II to VI. Accordingly, the claims of Groups I to VI are not independent of each other. Similarly, the claims of Groups VII to XII all define a gene delivery compound comprising a single chain binding polypeptide and a lipid associating moiety and the claims of Group VII are generic to those of Groups VIII to XII. Accordingly, it is abundantly clear that the claims of Groups VII to XII are not independent of each other. Moreover, the claims of Groups I to VI and Groups VII to XII are not independent of each other because they all define a compound comprising a single-chain binding polypeptide linked to a moiety which allows for the polypeptide to be associated with a nucleic acid to be delivered in gene therapy. The moiety may be either associated directly with the nucleic acid, in which case it would be the nucleic acid-binding moiety of the claims of Groups I to VI, or it may be associated with a lipid-containing structure which in turn is associated with the nucleic acid, in which case it would be the lipid-associating moiety of the claims of Groups VII to XII. Accordingly, the nucleic acid-binding moiety of the claims of Groups I to VI and the lipid-associating moiety of the claims of Groups VII to XII are related to each other. Given the above, the embodiments of the invention as defined by the claims of the various claim groups are not independent of each other.

The Examiner has recognized apparently that the claim groups do not define independent inventions because he has not characterized them as being independent. Moreover, the Examiner has not explained why he considers the claims to be directed to independent inventions. Consequently, the Examiner has issued a Requirement that is deficient because there is no explanation of why the various claims groups are considered to define independent subject matter.

In addition to the above, it should be noted that, as the claims of Group I are generic to the claims of Groups II to VI, the claims of these groups are not patentably distinct over each other. A similar situation exists between the claims of Group VII and those of Groups VIII to XII. Accordingly, the Examiner has not established that the claims are "distinct" under the definition of that term as summarized in the MPEP at §802.1.

Given the above, the Examiner has failed to establish that the above claim groups are independent and distinct from each other, as required by 35 U.S.C. §121. Accordingly, the Examiner's Requirement for Restriction should be withdrawn.

In his Requirement, the Examiner noted that, if the claims of Group I are elected for further prosecution, applicants must elect a species of the compound defined therein to which the claims shall be restricted if no generic claim is held to be allowable. According to the Examiner, the species are defined by the type of marker to be bound by the compound, the nucleic acid binding moiety, the therapeutic gene to be bound, and the conjugate formed.

With respect to the conjugate formed, the Examiner has indicated that the conjugates defined by the claims are: C6ML3-9 sFv'-H1; C6ML3-9 sFv'-P1; and C6ML3-9 sFv'-SP. Applicants note, however, that it is possible also for conjugates of the present invention to include effector and/or spacer sequences such as those defined by the claims. However, conjugates of this type are not provided for by the Examiner's definition of the conjugates. Accordingly, the election with respect to the conjugates should be between the following: C6ML3-9 sFv'-H1 or its derivatives; C6ML3-9 sFv'-P1 or its derivatives; and C6ML3-9 sFv'-SP or its derivatives. Applicants will therefore proceed with the election with the above-revised definition for the species.

Applicants elect, with traverse, the species of applicants' invention in which the marker to be bound is erbB2, the nucleic acid binding moiety is salmon protamine, the conjugate is G6ML3-9sFv'-SP or its derivatives, and the therapeutic gene is a tumor suppressor gene. Claims 1, 2, 4 to 8, 16 to 26, 29, and 52 read on this species.

While applicants have elected a species, it is submitted respectfully that the different types of markers to be bound by the compound serve the same purpose, that being a site for binding the compound, and operate by the same means, that being their affinity for the single chain polypeptide. The different types of nucleic acid binding moieties serve the same purpose, that of binding a nucleic acid, and operate by the same means, that being their affinity for the nucleic acid. The different types of conjugate serve the same purpose, that of binding both a nucleic acid and a marker on a cell, and operate by the same means, that being their affinity

for both the nucleic acid and a marker. It appears, therefore, that a proper search of the subject matter of one species of applicants' invention cannot be done except that a search is conducted for the subject matter of all species. This is so because the subject matter of the species is so interrelated.

In addition to the above, applicants assert respectfully that the Examiner's characterization of the species for election is improper because the species ought not be defined by the type of therapeutic gene bound. Applicants would like to emphasize that, unlike the case with the above marker to be bound, the interaction between the nucleic acid binding moiety and the therapeutic gene may be non-specific. For example, the nucleic acid binding moiety may be cationic and therefore bind non-specifically DNA which is anionic. Accordingly, it is the case that it is possible to use the same gene-delivery compound regardless of what therapeutic gene is to be bound and therefore distinct species of the invention are not defined by what therapeutic gene is bound by the compound. This being the case, applicants assert that the use of the therapeutic gene to be bound in defining the species of applicants' invention to be improper.

For the reasons expressed above, applicants traverse respectfully the Examiner's election of species requirement.

In view of the foregoing, an early and favorable Action is requested respectfully.

This Request is accompanied by a Petition for Extension of Time to respond to the Examiner's Action.

Respectfully submitted,

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